

UNITED STATES DEPARTMENT OF COMMERCE

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 APPLICATION NO.
 FILING DATE
 FIRST NAMED INVENTOR
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LISA A HAILE PH D GRAY CARY WARE & FREIDENRICH LLP 4365 EXECUTIVE DRIVE SUITE 1600 SAN DIEGO CA 92121-2189 EXAMINER
SOUAYA, J

ART UNIT PAPER NUMBER
1655

DATE MAILED: 05/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Application No.

Applicant(s)

09/687,246

Office Action Summary

Examiner

Art Unit

Nelson et al

1655 Jehanne Souaya -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). **Status** 1) X Responsive to communication(s) filed on Oct 12, 2000 2b) X This action is non-final. 2a) This action is **FINAL**. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. Disposition of Claims is/are pending in the application. 4) X Claim(s) 1-85 4a) Of the above, claim(s) _______ is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) ______ is/are rejected. is/are objected to. 7) Claim(s) are subject to restriction and/or election requirement. 8) X Claims 1-85 **Application Papers** 9) \square The specification is objected to by the Examiner. 10) The drawing(s) filed on ______ is/are objected to by the Examiner. 11) ☐ The proposed drawing correction filed on ______ is: a) ☐ approved b) ☐ disapproved. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). a) All b) Some* c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3.
Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). Attachment(s) 18) Interview Summary (PTO-413) Paper No(s). 15) Notice of References Cited (PTO-892) 19) Notice of Informal Patent Application (PTO-152) 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 20) Other: 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s).

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DETAILED ACTION

Election/Restriction

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-51, and 76-85, drawn to nucleic acids and methods for detecting hepatic cell proliferative disorder using nucleic acid based assays, classified in class 536, subclass 23.1 and class 435, subclass 6 respectively.
 - II. Claims 52-64, drawn to methods of detecting hepatic cell proliferative disorder using polypeptide based assays, classified in class 435, subclass 7.1.
 - III. Claims 65-75, drawn to methods of treating a hepatic cell proliferative disorder, classified in class 514, subclass 44.
- 2. The inventions are distinct, each from the other because of the following reasons: The inventions of Groups I, II, and III are patentably distinct from each other because the methods of detecting a cell proliferative disorder using nucleic acid based assays (Group I), methods of detecting a cell proliferative disorder using polypeptide based assays and immunoassays (Group II) and a method of treating a cell proliferative disorder are unobvious over each other. The method steps of each invention are not required to perform the methods of any of the other two inventions. Furthermore, the methods require different reagents, reaction conditions and reaction parameters.

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3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

- 4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II or Group III, restriction for examination purposes as indicated is proper.
- 5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
- 6. A telephone call was made to Lisa Haile on 3/27/2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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Any inquiry concerning this communication or earlier communications from the examiner 8. should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Thursday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Patent examiner

Opril 27,2001

N. Gary Jones

Supervisory Patent Examiner Technology Center 1600